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IN THE UNITED STATES DISTRICT COURT

DISTRICT OF ARIZONA

In Re Bard IVC Filters Products Liability Litigation	No. MD-15-02641-PHX-DGC **PLAINTIFFS' REPLY IN SUPPORT OF MOTION TO EXCLUDE DEFENSE EXPERT OPINIONS UNDER FED. R. EVID. 702 BASED ON THEIR USE OF THE CRIMINAL LAW STANDARD OF CERTAINTY (DOC. 7324)**

INTRODUCTION

Bard's opposition to Plaintiffs' motion misstates Plaintiffs' position and omits material facts. Plaintiffs address these issues in this reply brief.

ARGUMENT

I. DRS. GRASSI AND MORRIS APPLIED THE WRONG LEGAL STANDARD IN DEVELOPING THEIR OPINIONS FOR LITIGATION.

Initially, Bard objects that Plaintiffs accuse its experts of being "too certain of their opinions," and argues that the preponderance of evidence standard does not prevent an expert from holding opinions to a very high level of certainty. Bard Mem. at 1. Bard's argument misses the point and misstates Plaintiffs' position; it confuses the level

confidence in an expert's opinion with the legal standard required *to form* an expert's opinion.

Bard also claims (on page 1 of its brief) that Plaintiffs' are complaining about "'standards' of their own creation." This is belied by the actual testimony of Drs. Grassi and Morris, set forth below. Both testified as to the standards that *they* employed as part of *their* methodology.

Bard's brief at pp. 5-6 attempts to conflate the experts' opinions about the limitations inherent in the studies in the medical literature[1] with the problem that Plaintiffs' advance in this motion: the use by these experts of a heightened standard for assessing the evidence and forming their opinions. Bard's experts can certainly point out limitations in the evidence without raising a *Daubert* issue, but that is not the problem at the core of Plaintiffs' motion.

While it is true that expert witnesses may permissibly hold their opinions to a high degree of certainty without raising a *Daubert* challenge, as noted in one of the cases cited by Bard (*Iplearn*), experts must nevertheless employ a methodology to evaluate the evidence and develop their opinions applying the proper legal standard. ("[A]n expert cannot base a decision on incorrect legal standards.") *See Iplearn v. Blackboard, Inc.*, No. CV 11-876 (RGA), 2014 WL 4967122, at *2 (D. Del. Oct. 2, 2014). "[A]ny step that renders [the expert's] analysis unreliable ... renders the expert's testimony inadmissible. This is true whether the step completely changes a reliable methodology or merely misapplies that methodology." *In re Silicone Gel Breast Implants Products Liability Litigation*, 318 F. Supp. 2d 879 (C.D. CA 2004)

[1] As noted in the *Reference Manual on Scientific Evidence*, and as recognized by many courts, all studies have limitations. "It is important to emphasize that all studies have "flaws" in the sense of limitations that add uncertainty about the proper interpretation of the results." *Reference Manual on Scientific Evidence*, (3d Ed. Federal Judicial Center, 2011), p. 553.

Plaintiffs do not take issue with opinions about which Bard's experts expressed certainty; rather, the problem here arises when experts in a civil product liability action decline to agree with a proposition based on the heightened, "beyond-any-reasonable-doubt" criminal law standard or "more than 90 percent" certain standard.[2] Thus, there is a meaningful difference between *holding* an opinion to a "more than 90 percent" or "beyond any reasonable doubt" level of certainty and using that heightened standard of certainty to analyze the medical evidence in *forming* an expert opinion, or agreeing or disagreeing with a relevant fact or opinion expressed by an opposing expert. Drs. Grassi and Morris applied the heightened standard *in forming their opinions*, to evaluate the medical literature evidence and to evaluate the opinions expressed by Plaintiffs' experts. Thus, their testimony will confuse and mislead the jury and prejudice Plaintiffs by requiring Plaintiffs—whether explicitly or implicitly—to prove their case to a much higher level of certainty than the law requires.

As *Daubert* instructs, "It would be unreasonable to conclude that the subject of scientific testimony must be 'known' to a certainty; arguably, there are no certainties in science." *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 590 (1993). Imposing a "certainty" standard on expert testimony for medical proof is "wholly inconsistent with *Daubert* and the fundamental premise of Rule 702." *McClellan v. I-Flow Corp.*, 710 F. Supp. 2d 1092, 1101 (9th Cir. 2010). Indeed, *Daubert* does not authorize courts or experts to increase the burden of proof beyond a preponderance of the evidence. *In re Ephedra Prods. Liab. Litig.*, 393 F. Supp. 2d 181, 193 (S.D.N.Y. 2005).

Dr. Grassi made it clear in his deposition that he *applied* a "beyond any reasonable doubt" standard to *form* his opinions and evaluate evidence before he would agree with it. After testifying that "there had not been a mechanism [to explain fractures], which has yet to be proven," Ex. 2, Grassi Dep. at 91:8-10, Dr. Grassi was asked to explain what

[2] Ex. 1, Morris Dep., at 143:20 ("more than 90 percent"); *see also* Ex. 2, Grassi Dep., at 94:10-11 ("beyond any reasonable doubt").

level of proof he would require. He responded that he needed a "convincing explanation," adding that "I would look for evidence *where I felt certain beyond any reasonable doubt*." Ex. 2, Grassi Dep. at 94:10-11. Dr. Grassi further testified that "overall," he applied this standard in developing his opinions in this litigation. *Id.* at 94:10-15. He also elaborated that more studies need to be done on whether longer indwell times increase the risk of complications "before I'm convinced…" *Id.* at 128:8-13. Thus, Dr. Grassi applied a criminal law standard of proof as part of his method when evaluating the evidence to form his opinions. He rejected propositions about fractures and indwell times and intends to explain to the jury, for example, that no fracture mechanism has been proven and that longer indwell times do not lead to increased risk of complications, when the standard he uses is far greater than the jury must use to evaluate the same evidence. Bard's brief simply ignores this testimony.

Similarly, Dr. Morris was asked, "What level of certainty *did you apply* to your opinions?" Ex. 1, Morris Dep. at 139:2-24. After describing his methodology for how he typically goes about assessing evidence, he concluded—without any intervening follow up questions, "…I approach the litigation using the … same methodology, essentially. So I would say a *high level of certainty*." *Id.* at 140:2-4. He testified that he used a "benchmark for 100 percent certain[ty]," *Id.*, at 141:22-23. He added: When I compare that to the literature that's available regarding IVC filters, there's basically no… comparison, so how can I make 100 percent certain opinions based on literature which is less than Level I or Level II evidence? *Id.*at 142:9-14. After Dr. Morris testified about "100 percent certain opinions," he was then asked:

> Q: So that's what you generally look for is more than 90 percent certainty for your opinions in this case?
>
> A: Generally speaking, yes.

Id. at 143:21-24.

Dr. Morris's testimony unequivocally shows that he was not testifying about how confident or certain he was in *expressing* his opinions; he was testifying about the methodology he used for *reaching* his opinions.

The *Daubert* inquiry focuses on the reliability of an expert's methodology, not the conclusions it generates. *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993); *City of Pomona v. SQM North America Corp.*, 750 F.3d 1036 (9th Cir. 2014). Employing an improper standard for assessing evidence and developing an opinion renders the expert's methodology unreliable. Drs. Morris and Grassi's testimony is not only inconsistent with the threshold required by *Daubert* and Rule 702; it is misleading and unhelpful to the jury in deciding the facts, and prejudicial to Plaintiffs. These opinions should therefore be excluded.

Bard either fails to understand--or misrepresents--Plaintiffs' position on this motion, when on page 1 of its brief Bard characterizes Plaintiffs' motion as complaining about experts who are "too certain of their opinions" and then states on page 8 of its brief: "Plaintiffs …[claim] …that because a medical expert is *permitted* to express a causation opinion without proving causation to a scientific certainty, that somehow precludes an expert from expressing *greater* than 51% certainty…." As detailed above, Bard's argument is flawed based on the straw man fallacy. Bard's opposition is based on mischaracterizing the Plaintiffs' position, and then arguing against the "straw man."[3]

The cases cited by Bard are inapposite. *Iplearn* and *Fosamax* involved patent disputes, where experts were challenged for the opposite of what occurred here—they presented opinions that tended to prove a relevant fact, but, standing alone, were not sufficient to meet the applicable burden of proof ("clear and convincing" in the patent

[3] A straw man is a common form of argument based on giving the impression of refuting an opponent's argument, while refuting an argument that was not presented by that opponent. One who engages in this fallacy is said to be "attacking a straw man." This type of argument is known as the straw man fallacy.

context). *Iplearn*, 2014 WL 4967122, at *2; *Formax, Inc. v. Alkar-Rapidpak-MP Equip., Inc.*, No. 11-C-298, 2014 WL 3057116, at *2 (E.D. Wis. July 7, 2014). This is a relevance argument, and these cases demonstrate the unremarkable proposition that evidence—including expert opinion—may be admissible "if it has any tendency to make a fact more or less probable than it would be without the evidence." Fed. R. Civ. P. 401. The opinions challenged here are the inverse because they are about conclusions *not* reached rather than opinions based on limited information. Similarly, *Ambrosini* did not address any argument that an expert applied a heightened standard to form opinions or before agreeing to a proposition. *Ambrosini v. Labarraque*, 101 F.3d 129, 138 (D.C. Cir. 1996).

II. DRS. MORRIS AND GRASSI WERE NOT COERCED INTO TESTIFYING ABOUT THE LEVEL OF CERTAINTY.

Bard next asserts that the Court should disregard the testimony of Drs. Grassi and Morris, claiming they were pressured or tricked at their depositions, suggesting that opposing counsel put words in their mouths. Bard Mem. at 1. Specifically, Bard complains that the experts were pressed "to assign a numerical level to the value of certainty that they applied to their opinions" even though it was difficult. *Id.* Bard goes so far as to claim that Plaintiffs' counsel, not the experts, suggested specific numerical values about the level of certainty "and invited the experts to agree or disagree." *Id.* Not true. The witnesses were neither pressured nor boxed in. Counsel simply followed up on Dr. Morris's comment that he used a "high level of certainty" to form his opinions, by asking if that meant an 80% level of certainty. Dr. Morris freely responded that it would be "more than 80 percent." Ex. 1, Morris Dep. at 143:19. Dr. Morris could have testified to any number—or range of numbers—he felt comfortable with, including a lower one, and Bard's counsel had the opportunity to ask questions to clarify.

III. THE EXPERTS' DEPOSITION TESTIMONY IS PART OF THE *DAUBERT* RECORD.

Finally, Bard maintains that Plaintiffs' *Daubert* challenge to Drs. Grassi and Morris is a non-issue that Plaintiffs created in their depositions, eliciting testimony the experts do not state in their reports. Bard Mem. at 1. This argument is spurious. It suggests that the *Daubert* inquiry is confined to the contents of an expert's Rule 26 report and that the expert's deposition testimony is irrelevant.

Ironically, Bard takes the opposite position when raising *Daubert* challenges to *Plaintiffs'* experts. Bard's *Daubert* motions are replete with attacks on statements Plaintiffs' experts made in their depositions. For example, Bard's motion to exclude Dr. Eisenberg cites his deposition testimony repeatedly over a span of 10 pages. [Doc. No. 7291 at 2-4, 6-9, 11, 13, 17]. And Bard's motion to exclude Dr. Betensky quotes her deposition testimony at length. [Doc. No. 7288 at 4, 7, 8-9, 11, 14-15].

The very purpose of deposing an expert witness is to explore and probe the substance, basis, and methodology of the expert's opinions. In testing the reliability and relevance of the testimony, it is important for the parties and the Court to know what methodology the experts used to evaluate the evidence and formulate their opinions. Because Drs. Morris and Grassi provided little or no substantive information about this issue in their reports, it was incumbent upon Plaintiffs' counsel to find out. The experts' deposition testimony provided that information and is part of the record the Court must use in screening their opinions under *Daubert.*

CONCLUSION

For the reasons stated above, and in Plaintiffs moving papers, the Court should grant Plaintiffs' Motion.

RESPECTFULLY SUBMITTED this 18th day of October, 2017.

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CERTIFICATE OF SERVICE

I hereby certify that on this 18th day of October, 2017, I electronically transmitted the attached document to the Clerk's Office using the CM/ECF System for filing and transmittal of a Notice of Electronic Filing.

/s/ Gay Mennuti